

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

June 10, 2009
Second Floor
Conference Room 2

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

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| CALL TO ORDER: | The meeting was called to order at 9:20AM. |
| PRESIDING: | David C. Kozera, Chairman |
| MEMBERS PRESENT: | Gill B. Abernathy John O. Beckner Willie Brown Gerard Dabney Jennifer H. Edwards Bobby Ison Leo H. Ross Michael E. Stredler Brandon K. Yi |
| STAFF PRESENT: | Elizabeth Scott Russell, Executive Director Cathy M. Reiniers-Day, Deputy Executive Director Caroline D. Juran, Deputy Executive Director Howard M. Casway, Senior Assistant Attorney General Sandra Whitley Ryals, Director, DHP Betty Revere, Administrative Assistant |
| QUORUM: | With ten members present, a quorum was established. |
| APPROVAL OF AGENDA: | An amended agenda was distributed prior to the beginning of the meeting. With one addition, discussion of the inspection "ticketing" program, the amended agenda was approved as presented. |
| APPROVAL OF MINUTES: | The Board reviewed draft minutes included in the agenda package. With no changes to the minutes, the minutes were approved as presented. |
| PUBLIC HEARING ON PROPOSED REGULATIONS FOR CHANGING EXPIRATION DATES: | The Board held a public hearing on proposed regulations to replace emergency regulations related to change in expiration dates for facilities. There was no comment offered on the proposed regulations during the hearing. |
| PUBLIC COMMENTS: | Beverley Soble, Virginia Health Care Foundation and Wendy Walter, Fairmont Crossing, Amherst, VA requested that the Board consider changing its regulations to allow Schedule II controlled substances to be maintained in the stat boxes for long term care |

facilities. Ms. Soble stated that nursing homes frequently receive orders for patients on nights and weekends when it is not possible to receive timely medications from pharmacies. Under the best circumstances, i.e. midweek and daytime, there is typically at least a six to eight hour delay in getting an ordered medication. She stated that there are other standards under CMS and VDH that are violated if patients are not receiving pain medication in a timely manner. She also stated that she has taken steps to explore all viable options; including obtaining discharge medications when patients are sent from the hospital to the nursing home, and the use of the automated dispensing devices (ADD), but these did not appear viable. Ms. Abernathy questioned why the ADD option was not feasible, and Ms. Walter explained that expense was the primary reason with the current reimbursement structure, but also, even if a home could afford one ADD, there is no one place to put it to be geographically accessible because of the distance from the device to other nursing units. Ms. Soble also stated that they had determined that MD, NC, and WV all allowed Schedule II drugs for first doses, but all did so under different processes.

As a result of the comments, the Chairman appointed a committee of the Board to include Mr. Beckner, Mr. Ross, and Mr. Yi to meet with representatives for nursing homes and long term care pharmacies to develop a recommendation for this issue. Ms. Russell stated that DEA would need to be consulted to ensure that any recommendation would not violate DEA regulations.

DHP DIRECTOR'S REPORT

Ms. Ryals briefly reported that the Health Care Workforce Center was progressing well in its mission. She reminded the Board that as of July 1, 2009, the name Health Practitioners' Intervention Program (HPIP) will change to Health Practitioners' Monitoring Program (HPMP) to reflect the monitoring rather than treatment nature of the program. She acknowledged Ms. Russell for her participation on the internal committee that developed recommendations for changes to the program to more closely align the program with the mission of DHP and effect cost savings, and her continued participation on the external committee with VCU to implement needed changes and efficiencies. Ms. Ryals also mentioned that the Department continued to do well with all three performance measures, and that she would have more details at a future meeting.

Ms. Ryals discussed the security breach of the Prescription Monitoring Program. She outlined all steps that had been taken by the Department from the moment the breach was discovered to the present, to include the dates and content of the various notifications. She stated that the matter is still under investigation, that it is a criminal matter, and that for this reason certain details

cannot be given at this time. She stated that the responsible party, if found, will be held accountable. In response to questions about future steps, Ms. Ryals stated that vulnerability assessments are being done on all systems, and that everything has been or is being reconfigured to assure security to the maximum extent possible.

Ms. Ryals stated that Q & A related to the breach, as well as advice for persons questioning possible identity theft, is available on the main page of the DHP website, and this information is frequently updated.

When asked about funding of the notifications and recovery effort, Ms. Ryals stated that expenses related directly to the PMP, such as notifications, are coming from the PMP budget. For other general expenses, such as increases in IT security, the expense will be spread across all boards, as is currently the process for handling other general expenses of the Department.

Ms. Ryals addressed the revenue and expenditure analysis letter in the agenda package. This analysis is required to be done at least once each biennium by Virginia law. The Board, at the current time, is in the position of having a surplus, but Ms. Ryals is not recommending that the Board reduce fees as it is anticipated that expenditures may be increasing primarily due to significant increases in IT costs. Ms. Ryals suggested that the Board wait until the September board meeting to take any action on the Department's recommendations. By this next meeting, actual year-end data will be available, and the Department hopes that it will have IT cost projections from VITA.

ELECTION OF OFFICERS

Mr. Kozera called for nominations for the office of Chairman. Mr. Ross nominated Jennifer Edwards. With no additional nominations, the Board voted unanimously to close nominations (motion by Brown, second by Beckner). On a voice vote, the Board elected Ms. Edwards as Chairman for the term July 1, 2009 through June 30, 2010. Mr. Kozera called for nominations for the office of Vice Chairman. Mr. Ross nominated Brandon Yi. With no additional nominations, the Board voted unanimously to close nominations (motion by Beckner, second by Edwards). On a voice vote, the Board elected Mr. Yi as Vice Chairman for the term July 1, 2009 through June 30, 2010.

LEGISLATION UPDATE:

Ms. Russell stated that the Board has one legislative proposal to review and approve, which is the annual scheduling bill included in the agenda package. This year, DEA has scheduled two new drugs that need to be added to the Virginia schedules, tapentadol to Schedule II and lacosamide to Schedule V.

Motion: **The Board voted unanimously to approve the legislative proposal for scheduling tapentadol and lacosamide as presented. (motion by Beckner, second by Stredler)**

The Board reviewed a legislative proposal initiated by the Office of Community Integration for People with Disabilities to amend the Drug Control Act to allow an unlicensed person to administer any normally self-administered drugs to a patient in a private residence. Current law restricts this to oral or topical drugs. The Board expressed no concerns about this legislation and took no action.

REGULATION UPDATE: Ms. Russell provided an update on current regulation processes to include that the final amendments to regulations from the periodic review are under review in the Governor's office. The proposed regulations on standards of conduct are also at the Governor's office.

PROPOSED REGULATIONS, DRUG DONATION PROGRAMS: The Board reviewed proposed regulations for drug donation programs to replace the emergency regulations currently in place until April 9, 2010. The proposed regulations are identical to the emergency regulations.

Motion: **The Board voted unanimously to adopt proposed regulations for drug donation programs as presented in the agenda package. (motion by Ross, second by Edwards)**

PETITION FOR RULEMAKING: The Board reviewed a petition for rulemaking from Eric Hampton requesting the Board to amend regulations to delete the requirement for a nurse's signature for delivery of drugs to an automated dispensing device in a hospital. The petition was published on April 13, 2009. The comment period ended on May 13, 2009. The Board received a number of comments on Townhall, all supportive of the petition, the majority from staff at Martha Jefferson Hospital.

Motion: **The Board voted unanimously to initiate the rulemaking process on the petition, and to publish a NOIRA. (motion by Ison, second by Yi)**

UPDATE ON MEDICAL EQUIPMENT SUPPLIERS AND VERBAL ORDERS: Ms. Russell reminded the Board that, at the last board meeting, there had been a discussion as to whether a medical equipment supplier could lawfully accept a verbal order or had to have a written order. A prescriber had complained to staff that a medical equipment supplier was forcing him to provide a written order if he tried to call in a prescription. The Board had requested that staff further research this issue before the June meeting to determine whether a guidance document was needed. Staff determined that

most medical equipment suppliers were accepting verbal orders in some cases for the purpose of not delaying care, but then were obtaining a written order as a standard practice since most all insurance plans require a written order for reimbursement of claims. Based on this information, Ms. Russell stated that she did not believe a guidance document was needed.

DELEGATION OF
APPROVAL OF REQUESTS
FOR A TESTING
ACCOMMODATION
PURSUANT TO THE ADA:

The Board reviewed a bylaw addition that would delegate to the Executive Director, the approval of additional testing time upon a request with the appropriate supporting documentation for an accommodation under the Americans with Disabilities Act (ADA). Requests for accommodations other than additional time will still be presented to the Board for review and decision.

Motion:

The Board voted unanimously to adopt the bylaws change presented in the agenda, delegating to the Executive Director, the review and approval of additional testing time as an ADA testing accommodation. (motion by Stredler, second by Ross)

AMENDMENT OF
GUIDANCE DOCUMENT
110-24:

The Board reviewed amendments to Guidance Document 110-24 to establish standards for the competency examination for applicants for licensure by endorsement who were initially examined prior to a nationally accepted examination. The first "national exam" was offered by NABP in 1975, but it was not until June 1, 1979 that all states were expected to use the NABP examination. Prior to this date, persons may very likely have taken and passed a state approved competency examination. The amendments to the guidance document provide that documentation of passing such examination is satisfactory evidence of meeting the same standard of competence required for licensure by examination in Virginia at that time. After June 1, 1979, an applicant must have passed the NABP examination.

Motion:

The Board voted unanimously to adopt the amendments to Guidance Document 110-24 as presented in the agenda. (motion by Beckner, second by Dabney)

DISCUSSION OF THE
INSPECTION PROCEDURES:

Ms. Russell stated that staff was continuing to work on electronic inspection forms, and the new procedures for leaving a pre-hearing consent order at the conclusion of the inspection by which a pharmacy could elect to pay monetary penalties for certain inspection violations. Mr. Ison expressed some concern that all deficiencies may not be appropriate for this type of process. Ms. Russell suggested that a committee meet prior to the next Board meeting to complete the work done by the previous committee and make a recommendation to the full board in September.

Mr. Kozera appointed Mr. Ison, Mr. Stredler, Ms. Edwards, and

himself to this committee. Ms. Russell stated that she would contact each member and find a mutually agreeable date for this meeting.

REPORT OF BOARD OF
HEALTH PROFESSIONS,
JENNIFER EDWARDS:

Ms. Edwards stated that BHP has been studying the need for licensing of certain emerging professions, specifically orthotists, prosthetists, medical interpreters, polysomnographers, surgical assistants and surgical technologists. She stated that BHP is contacting other agencies to determine who should regulate medical interpreters, and BHP plans to move ahead with looking into the potential for licensing surgical assistants and technologists. The following is an excerpt from the May 12, 2009 BHP minutes:

Orthotists and Prosthetists – The Committee recommended that the professions not be regulated and the motion of the Committee was seconded by Ms. Hughes and carried unanimously.

Medical Interpreters – The Committee requested that staff contact the Department of Health and the Department of Medical Assistance Services to seek their input regarding the state's oversight of the profession.

Polysomnographers – The Committee requested that Mr. Crow present his presentation to the Respiratory Therapy Advisory Committee for their review and recommendation back to the Board.

Surgical Assistants and Surgical Technologists – The Committee requested a public hearing for additional public comment prior to rendering a recommendation to the full Board.

REPORT OF DISCIPLINARY
CASELOAD

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of June 9, 2009: there were 79 cases at the enforcement level, 31 cases at the probable cause level, 5 cases at the informal conference level, 1 case at the formal hearing level and 12 cases at the APD level. Further, she stated that the Board had a total of nine Priority A cases; eight at the enforcement level, and one at the formal hearing level. Since the last board meeting on March 10, 2009, 75 cases have been closed.

REQUEST FOR TESTING
ACCOMMODATION:

Ms. Russell stated that the Board had received a request for a testing accommodation other than additional time, pursuant to a disability, that the Board needed to review.

Motion:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711 (A) (7) of the Code of Virginia for the purpose of consultation with legal counsel and briefings by staff members pertaining to probable litigation. Additionally,

it was moved that Scotti Russell, Cathy Reiniers-Day, Caroline Juran, and Howard Casway attend the closed meeting because their presence was deemed necessary. (motion by Stredler, second by Ross)

Motion:

The Board voted unanimously to certify, to the best of its ability, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting just concluded. (motion by Stredler, second by Ross)

Motion:

The Board voted unanimously to grant the request by Jaxon L. Zimmerman for double time to take the pharmacy technician examination, but denied Mr. Zimmerman's request for a reader based on the fact that the ability to read is an integral part of the duties of a pharmacy technician, and the reading of the examination is the only means for the Board to assess an applicant's ability to read and comprehend written material. (motion by Stredler, second by Brown)

ADJOURN:

With all business concluded, the meeting adjourned at 12:48 PM

Elizabeth Scott Russell
Executive Director

David C. Kozera, Board Chairman

Date